K133316

510(K) SUMMARY

Adhese® Universal

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passion vision innovation

Contact: Donna Marie Hartnett

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FEB 11 2014

Date Prepared: November 8, 2013

Proprietary Name: **Adhese® Universal**

Classification Name: Dental Adhesive (872.3200) (Classification Code KLE))

Predicate Devices: 3M Adhesive EXL 759 (K110302) (Scotchbond Universal))

Device Description: Adhese® Universal is a light-curing single-component dental adhesive for enamel and dentin.

The predicate device to which Adhese Universal cement has been compared is Scotchbond Universal (3M Adhesive EXL 759 (K110302). For this application, Adhese Universal has been compared to its predicate with regard to chemical composition, performance data and indications for use. The comparison shows that Adhese Universal is substantially equivalent to the predicate device.

Intended Use: – Direct-placed light-curing composite and compomer restorations.
– Direct-placed core build-ups with light-, self- and dual-curing composites.
– Repair of fractured composite and compomer restorations.
– Adhesive cementation of indirect restorations with light- and dual-curing luting composites.
– Sealing of prepared tooth surfaces before temporary / permanent cementation of indirect restorations.
– Desensitization of hypersensitive cervical areas.

Technological Characteristics: The device design, i.e. delivery form, and intended use of Adhese Universal and the predicate device are the same except Adhese Universal is also marketed in a Vivapen delivery form. The Vivapen is a state of the art applicator for dental adhesives, which is successfully in use with other IVAG dental adhesives (e.g. AdheSE One F, ExciTE F). The composition of the subject device has been modified from the predicate.

Testing Summary: The device was tested for shear bond strength to dentin and enamel using the standard shear bond strength method (see ISO 29022 for sample preparation) and the results from testing demonstrate that Adhese Universal is substantially equivalent to the predicate device. Biocompatibility testing and evaluation was also carried out according to ISO 10993.

CONCLUSION: The above data and analysis demonstrates that Adhese® Universal is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 11, 2014

Ivoclar Vivadent, Incorporated
Donna Marie Hartnett, Esq.
Director QA/Regulatory Affairs
175 Pineview Drive
Amherst, New York 14228

Re: K133318
Trade/Device Name: Adhese Universal
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: Class II
Product Codes: KLE, LBH
Dated: November 8, 2013
Received: November 14, 2013

Dear Ms. Hartnett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer -S FDA for

Erin I. Keith M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K133319

Device Name: Adhese® Universal

Indications For Use:

- Direct-placed light-curing composite and compomer restorations.
- Direct-placed core build-ups with light-, self- and dual-curing composites.
- Repair of fractured composite and compomer restorations.
- Adhesive cementation of indirect restorations with light- and dual-curing luting composites.
- Sealing of prepared tooth surfaces before temporary / permanent cementation of indirect restorations.
- Desensitization of hypersensitive cervical areas.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S. Runner -S
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